K060488

JUN - 8 2006

DermaTech Medical
1971 S. Estes St.
Lakewood, Colorado 80227
Tel: 303.763.5787
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Premarket Notification [510(k)] Summary

Submitter:	DermaTech Medical
Address:	1971 S. Estes St. Lakewood, Colorado 80227
Contact Person:	Glenn Thibault (Consultant)
Address:	102 Heritage Ave Castle Rock, Colorado 80104
Telephone Number:	303.596.1108
FAX Number:	303.320.4664
Date Prepared:	February 20, 2006
Trade Name:	DermaTech Medical Sterile IV Holder
Common Name:	DermaTech Medical Sterile IV Holder
Classification Name:	IV Administration Set
Predicate Devices:	BD Posiflow Positive Displacement Device Vital Care IV Administration Set Nexus TKO Needleless Access Device

Description:

The DermaTech Sterile IV Holder is a sterile tape-less anchoring system comprising of Non-pyrogenic, PVC tubing with ABS male and female luer locks at each end, two Low Density Polyethylene Clam Shell tubing holders with a Polypropylene Hybrid Stretch Bonded Laminate Velcro strap. Once a needle or catheter is inserted into the artery or vein the DermaTech Sterile IV Holder is attached and provides a tape-less securing method to administer IV fluids.

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Intended Use:

DermaTech IV Holder is a device intended to administer fluids from a container to a patient's vascular system through a catheter or needle inserted into a patient's artery or vein.

Technological Characteristics Comparison:

All Materials are similar to the predicate devices; the product is used for IV administration in a tapeless manner. The Set is connected utilizing common male and female Luer Locks.

Non-clinical Tests Support Substantial Equivalence:

The current devices where compared for flow rate, backpressure leakage, and vacuum Leakage to the DermaTech IV Holder.

Conclusions from Non-clinical Tests:

The comparison test verifies the predicate devices and the DermaTech IV Holder are substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2006

DermaTech Medical, Incorporated
C/O Mr. Glenn Thibault
Consultant
G & N Consulting
102 Heritage Avenue
Castle Rock, Colorado 80104

Re: K060488
Trade/Device Name: DermaTech IV Holder
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, KMK
Dated: April 21, 2006
Received: April 21, 2006

Dear Mr. Thibault:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

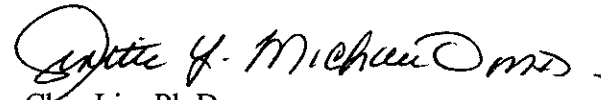
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060488

Device Name: DermaTech IV Holder

Indications For Use: The DermaTech IV Holder is intended as an intravascular administration set to administer fluids through a catheter or needle inserted into a patients artery or vein.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

...on Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...k) Number: K060488